

Public Statement:

ARBenefits provides a limited benefit for the treatment of Erectile Dysfunction.

In general, treatment of erectile dysfunction is limited to treatment of dysfunction caused by diabetic neuropathy, spinal cord injury, radical prostate surgery or vascular occlusion in the penis.

Treatment consists of counseling, oral medications, injectible medications, external devices, penile prostheses and penile revascularization.

Treatment of psychological causes of erectile dysfunction through the Mental Health benefit is treated the same as any other mental health treatment.

Medical Policy Statement:

- A. Diagnosis: Diagnostic evaluation of erectile dysfunction is a covered benefit and may include any of the following:
 - Comprehensive history and physical examination (including medical and sexual history and psychosocial evaluation)
 - Mental health visit
 - Blood glucose
 - Complete blood count
 - Creatinine
 - Hepatic panel
 - Lipid profile
 - Prostate specific antigen
 - Serum testosterone

- Tests for evaluation of pituitary dysfunction (e.g., measurement of luteinizing hormone (LH), follicle-stimulating hormone (FSH), and prolactin levels) if serum testosterone level is below normal
- Thyroid function studies
- Urinalysis
- Nocturnal penile tumescence (NPT) (54250) testing using the postage stamp test or the Snap Gauge test is considered medically necessary where clinical evaluation, including history and physical examination, is unable to distinguish psychogenic from organic impotence and any identified medical factors have been corrected
- NPT testing using the RigiScan is considered medically necessary only where NPT testing is indicated, and the results of postage stamp or Snap-Gauge testing are equivocal or inconclusive
- Pharmacological response test (PRT) (54235) for erectile dysfunction (using vasoactive drugs, e.g., papaverine HCl, phentolamine mesylate, prostaglandin E1) is covered only when administered after the diagnosis is established as one of the covered diagnoses.
- Duplex scan (Doppler and ultrasound) in conjunction with intracorporeal papaverine.
- Dynamic infusion cavernosometry (54231) and cavernosography (54230 and 74445) only for members who are to undergo revascularization procedures and meet medical necessity criteria for penile revascularization (see below).
- Pudendal arteriography (angiography) only for members who are to undergo penile revascularization and meet the medical necessity criteria for penile revascularization (see below). The following diagnostic tests for erectile dysfunction are considered experimental/investigative;
- Corpora cavernosal electromyography (EMG)
- Dorsal nerve conduction latencies
- Evoked potential measurements
- Penile plethysmography (54240)
- Iron binding capacity
- Prostatic acid phosphatase.
- B. Treatment: Treatment coverage is limited to erectile dysfunction caused by diabetic neuropathy, spinal cord injury or prostate surgery. The therapies are:
 - a. <u>Counseling</u>: Counseling may be covered (within the plan limitations) when the counseling is directed at sexual dysfunction caused by a listed disease process, and when the counseling is expected to produce significant results within a short course of treatment. Counseling for sexual dysfunction is covered under the mental health/substance abuse coverage provisions of the plan.
 - b. Oral and Transdermal Medications

- Sildenafil citrate (Viagra), vardenafil hydrochloride (Levitra or Staxyn) and tadalafil (Cialis) are covered subject to the limitations of the drug benefit.
- ii. Exogenous testosterone replacement therapy, including Transdermal preparations, is considered experimental and investigational for the treatment of non-hypogonadal impotence because its effectiveness in non-hypogonadal impotence has not been established.
- iii. Topical cream or gel containing vasodilators, such as verapamil cream, is considered experimental and investigational for the treatment of erectile dysfunction because their effectiveness for this indication has not been established.
- c. <u>Injectible Medications:</u> Self-administered injectible medications for the treatment of erectile dysfunction are eligible for coverage for the listed diagnoses and include:
 - i. Injections into the corpus cavernosa to cause an erection (papaverine, asprostadil, phentolamine) and,
 - ii. MUSE (Medicated Urethral System for Erection) method of treatment for erectile dysfunction that involves inserting medication through a small catheter into the urethra.

Titrating doses of injectible impotence medications administered in a physician's office and the accompanying office visits are considered medically necessary. This includes in office titrating doses of papaverine, alprostadil (prostaglandin E1 or Caverject) and phentolamine. Except for phentolamine, which is not generally used alone, these drugs can be used alone or in combination. The drug MUSE, a pellet from of alprostadil, is also used as an alternative to alprostadil injections.

Diagnostic injections of impotence medications by the treating physician are also considered medically necessary.

- d. <u>External Devices:</u> The external penile vacuum pump device is medically necessary durable medical equipment (DME):
 - i. When it is prescribed by a physician as an alternative to other therapies for erectile dysfunction; and
 - ii. When medication therapy has proven ineffective; and
 - iii. When the prescription is to treat one of the covered diagnoses as the cause of erectile dysfunction.
- e. <u>Implantable Devices</u> Implantation of semi-rigid penile prostheses or inflatable penile prostheses (implantable penile pumps) is considered medically necessary for members:
 - i. Who have documented physiologic erectile dysfunction caused by one of the covered diagnoses; and
 - ii. Who have failed medical therapy: or
 - iii. For whom medical therapy is contraindicated.
- f. <u>Surgical Revascularization:</u> Penile revascularization for vasculogenic erectile dysfunction is considered medically necessary **only** in men less than 50 years old who meet **all** of the following criteria:

- i. The erectile dysfunction is the direct result of an arterial injury caused by blunt trauma to the pelvis and/or perineum; and
- ii. A focal blockage of arterial inflow is demonstrated by duplex Doppler ultrasonography or arteriography; **and**
- iii. Diagnostic work-up reveals normal corporeal venous function; and
- iv. Member is not diabetic and has no evidence of systemic vascular occlusive disease; **and**
- v. Member is not actively smoking.

Consistent with clinical guidelines of the American Urological Association¹, arterial reconstructive procedures, dorsal vein arterialization procedures, or penile venous occlusive surgery (e.g., venous ligation, dorsal vein ligation) in men with erectile dysfunction secondary to arteriosclerotic occlusive disease is experimental and investigational because such procedures have not been proven to be effective.

g. Peyronie's Disease

- i. Plaque Excisions and Venous Graft Patching: Surgical correction of Peyronie's disease (e.g., plaque excisions and venous graft patching, tunica plication, Nesbit tuck procedure) is considered medically necessary for the treatment of members with Peyronie's disease lasting for 12 or more months with significant morbidity who have failed conservative medical treatment.
- ii. Extracorporeal Shock Wave Therapy (ESWT) is considered experimental and investigational for Peyronie's disease because of a lack of evidence from prospective randomized controlled clinical studies of the effectiveness of ESWT for this indication

Codes Used In This BI:

- 37788 Revascularization penis
 54230 Procedure for cavernosc
- 54230 Procedure for cavernosography
- 54231 Dynamic cavernosometry
- 54235 Penile injection
- 54240 NPT
- 54360 Penis plastic surgery
- 54400 Insert semi-rigid prosthesis
- 54401 Insert self-contd prosthesis
- 54405 Insert multi-comp penis pros
- 54406 Remove muti-comp penis pros
- 54408 Repair multi-comp penis pros 54410 Remove/replace penis prosth
- 54411 Remov/replc penis pros comp
- 54411 Remov/repic penis pros comp 54415 Remove self-contd penis pros
- 54416 Remv/repl penis contain pros
- 54417 Remv/replc penis pros compl
- 74445 Cavernosography
- L7900 Male vacuum erection penis

References:

- 1. American Urological Association; Guideline for management of erectile dysfunction at:
 - http://www.auanet.org/timssnet/products/guidelines/main_reports/edmgmt/chapter1.pdf
- National Institute for Clinical Excellence (NICE). Interventional procedures overview of extracorporeal shock wave therapy for Peyronie's disease. IPP Procedure No. 182. London, UK: NICE; March 2003. Available at: http://www.nice.org.uk/pdf/ip/182overview.pdf
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- Mizuno I, Fuse H, Fujiuchi Y. Snap-Gauge band compared to RigiScan Plus in a nocturnal penile tumescence study for evaluation of erectile dysfunction. Urol Int. 2003;71(1):96-99.
- 8. Broderick GA. Evidence based assessment of erectile dysfunction. Int J Impot Res. 1998;10 Suppl 2:S64-S73, S77-S79.
- 9. Urciuoli R, Cantisani TA, Carlinil M, et al. Prostaglandin E1 for treatment of erectile dysfunction. Cochrane Database Syst Rev. 2004;(2):CD001784.
- 10. Hauck EW, Mueller UO, Bschleipfer T, et al. Extracorporeal shock wave therapy for Peyronie's disease: Exploratory meta-analysis of clinical trials. J Urol. 2004;171(2 Pt 1):740-745.

Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

Last modified by: SCS Date: 06/13/2012